# IMPROVED APPARATUS AND METHOD FOR OSSICULAR FIXATION OF IMPLANTABLE HEARING AID ACTUATOR

## FIELD OF THE INVENTION

The present invention relates to an apparatus and method for interfacing an implantable hearing aid system with a patient's auditory system, and more particularly, to a fixation apparatus and method which yields enhanced energy transfer between an implantable actuator and the ossicular chain of a patient.

## BACKGROUND OF THE INVENTION

Fully-implantable and semi-implantable hearing aid systems typically employ some form of actuator to stimulate the ossicular chain and/or tympanic membrane in the middle ear of a patient. By way of primary example, implantable actuators may comprise an electromechanical transducer having a vibratory member positioned to mechanically stimulate the ossicular chain via axial vibrations communicated therebetween (see e.g., U.S. Patent No. 5,702,342).

As may be appreciated, the utilization of an implantable hearing aid actuator of the above-noted nature entails surgical positioning of the actuator within the mastoid process of a patient's skull. Such positioning typically requires the insertion of the actuator through a hole drilled in the mastoid process. Then, a distal end of an interconnected vibratory member is located immediately adjacent to a desired location along the ossicular chain (e.g., the incus).

In conjunction with such placement, the present inventors have recognized the importance of achieving a high degree of mechanical coupling between the vibratory member of an actuator and the ossicular chain in order to optimize performance. More particularly, the inventors have recognized that mechanical coupling may be significantly enhanced by inducing tissue interconnection with a vibratory member after implantation and/or by providing a degree of lateral loading between the vibratory member and ossicular chain. In turn, energy transfer is improved, thereby enhancing a patient's assisted hearing.

## SUMMARY OF THE INVENTION

In view of the foregoing, a general objective of the present invention is to provide a hearing aid apparatus and method that improves mechanical coupling between the vibratory member of an implantable actuator and the ossicular chain of a patient.

A related objective of the present invention is to provide for improved ossicular coupling by enhancing tissue interconnection between an implantable vibratory member and the ossicular chain of a patient.

Another related objective of the present invention is to provide for improved ossicular coupling by achieving a degree of lateral loading between an implantable vibratory member and the ossicular chain of a patient.

Yet a further related objective of the present invention is to provide for improved ossicular coupling in a manner that is relatively easy and inexpensive to implement.

One or more of the above objectives and additional advantages may be realized by an inventive fixation apparatus that comprises a proximal end for interconnection to a vibratory member of an implantable hearing aid actuator and a distal end for issue interconnection with, and preferably direct physical contact with some member of the ossicular chain of a patient (e.g., the incus). The fixation apparatus further includes a body portion extending between the proximal end and the distal end.

In one aspect of the invention, the body portion of the fixation apparatus may comprise at least one surface discontinuity for inducing patient tissue attachment thereto after implantation of the fixation apparatus. Such discontinuity may be defined by surface pores and/or surface asperities and/or by one or more complex surfaces such as grooves, depressions, holes, slots, recesses or the like at the distal end or along the body portion of the fixation apparatus.

In one arrangement, the fixation apparatus may be fabricated utilizing a biocompatible material that yields surface pores and/or asperities, such pores or asperities being of a size sufficient to permit tissue infiltration after implantation. For such purposes, and by way of example only, the fixation apparatus may comprise a ceramic material (e.g., aluminumoxide), a plastic material (e.g., polytetrafluroethylene (PTFE), polyethylene or polydimethylsiloxane), or a composite material (e.g., PTFE - carbon fiber, PTFE - aluminumoxide, or aluminum oxide -zirconium). Such materials may be integrally molded into or otherwise coated over a core body to define the fixation apparatus. In the later regard, examples of preferable outer coating materials include

hydroxyapatite, hydroxyapatile in an elastomeric matrix, or tricalciumphosphate with fibrigen glue.

As noted above, complex surface shapes may also advantageously define one or more surface discontinuities. In one arrangement, at least one slot may be provided which extends across the distal end and rearwardly through part of the body portion of the fixation apparatus. In a related arrangement, two transverse slots may be provided which extend from the distal end rearwardly through a part of the body portion. In an additional embodiment, a recessed ring may be defined around the body portion.

In yet a further arrangement, the body portion of the fixation apparatus may comprise one or more pairs of adjacent enlarged and reduced sections, wherein corresponding lip portions are defined therebetween. By way of example, the body portion may comprise a first frusto-conical section which proximally adjoins an adjacent reduced section (e.g., a cylindrical section), thereby defining an annular, stepped-down lip therebetween. In another arrangement, two frusto-conical sections may defined within the body portion with a reduced body section proximally located adjacent to each of the frusto-conical sections to define two corresponding lips. As may be appreciated, the utilization of configurations which define stepped-down lips from a distal end to proximal end perspective serves to enhance long term coupling since tissue growth which occurs after implantation adjacent to the lip portions will restrict undesired retraction (e.g., rearward movement) of the fixation apparatus.

In a related aspect of the present invention, the body portion of the fixation apparatus may comprise one or more tapered surfaces which angle outwardly from the distal end. Such a configuration facilitates insertion of the distal end into an opening defined at a desired location along the ossicular chain of a patient, thereby yielding an arrangement in which the distal end of the fixation apparatus may actually be seated within the ossicular opening to enhance mechanical coupling therebetween. Further, the noted arrangement facilitates removal, or disengagement, of the fixation device from the ossicular chain if so desired. Additionally, in certain arrangements a degree of outward, or lateral, loading on the sidewalls of the ossicular opening may be realized.

In yet another aspect of the present invention at least a subportion of the body portion of the fixation apparatus may be oriented so that a center axis thereof is not coaxially aligned with a center axis of an opening defined at a desired interface location along the ossicular chain of a patient. Further, at least the subportion of the body portion

may comprise a material that resiliently accommodates a degree of deflection so that, upon insertion of the distal end of the fixation apparatus into the ossicular opening, the body portion contacts a sidewall of the ossicular opening and is deflected to apply an outward, or lateral, loading on the sidewalls of the ossicular opening. In this regard, it is preferable that the body portion be provided so that, during insertion of the distal end into an ossicular opening, a ratio of the axial force to radial force applied at the ossicular opening site is maintained at less than about 10 to 1; preferably with no more than about 1.2 grams of axial force being applied. In the latter regard, after inserted placement of the distal end, substantially no axial force should be applied at the ossicular opening, while application of the lateral loading force should continue, thereby yielding enhanced coupling. To achieve the desired functionality, at least the noted subportion of the fixation apparatus may comprise a material having a modulus of elasticity in tension of at least about $1 \times 10^7$ psi. By way of example, the subportion of the body portion may comprise a metal such as a titanium, a titanium alloy, (e.g., nickel titanium), hardened platinum (e.g., cold-worked), a platinum alloy (e.g., platinum iridium), or a gold-plated stainless steel. Of note, a metallic core body may also be utilized with a ceramic material coating for tissue attachment purposes as referenced above.

When one or more slots are provided as described above, two or more leg members may each correspondingly define deflectable distal subportions of the body portion. Further, the distal outer surfaces of each of the leg members may be tapered as noted above. More particularly, the distal end of the fixation apparatus may have a maximum cross-dimension, (i.e. diameter) that is less than the minimum cross-dimension of a defined ossicular opening, while the distal outer tapered surfaces of the leg members may combinatively define a maximum cross dimension that is greater than the maximum cross-dimension of the ossicular opening. As such, upon insertion of the distal ends of the leg members into the ossicular opening the leg members may contact the internal sidewalls and gradually deflect inward toward a center axis of the fixation apparatus to yield lateral loading for enhanced mechanical coupling. Additionally, the outer surfaces of one or more of the leg members may be defined to angle outwardly from the proximal end of the fixation apparatus to an adjoinment region with a corresponding tapered surface at the distal end. Such a configuration may be utilized to increase the magnitude of outward mechanical loading per unit distance of distal end insertion into an ossicular opening.

In yet another aspect of the present invention, at least a subportion of the body portion may comprise a shape memory material such as titanium or a titanium alloy (e.g., nickel titanium). The subportion maybe advantageously conditioned for automatic activation at temperatures above predetermined minimum body temperature. More particularly, upon activation the body subportion may be provided to change from a first configuration to a second configuration, wherein lateral loading within an ossicular opening may be readily achieved.

In one arrangement, a distal end slot may define opposing leg members in the body portion, each of which leg members comprise a shape memory material. Upon activation, the opposing leg members are conditioned to collectively change from a closed, or collapsed, V-shape configuration to an opened, or expanded, V-shape configuration. As may be appreciated, activation may be automatically realized after surgical placement as the fixation apparatus is heated to bodily temperatures.

In a related aspect of the present invention, a fixation apparatus may comprise a spring member fabricated from a shape memory material. In turn, the body portion of the fixation apparatus may be sized to receive the spring member and adapted to be deflectable from a first configuration to a second configuration upon activation of the spring member. By way of example, a shape memory spring member may be disposed within a slot extending across and rearwardly from the distal end of a fixation apparatus, wherein activation of the spring member (e.g., upon heating to bodily temperatures after surgical placement) laterally deflects opposing leg members outwardly to achieve a degree of lateral loading within an ossicular opening.

In view of the foregoing, it may be appreciated that the present invention also contemplates an inventive method for enhancing ossicular coupling of an implantable hearing aid actuator. The method includes the step of defining an opening in the ossicular chain of a patient (i.e. via laser ablation). The method further includes the step of positioning the distal end of a fixation apparatus into ossicular opening. In conjunction with such positioning the method may further entail the application of a lateral loading force by the fixation apparatus to the internal sidewalls of the defined opening to yield enhanced mechanical coupling therebetween. Alternatively and/or additionally, the method may provide for inducing tissue interconnection between a fixation apparatus and ossicular site by providing surface pores, surface asperities and/or complex surface shapes along the body portion.

As will be understood, the inventive method may utilize a fixation apparatus comprising one or more of the above-noted features. In particular, the ossicular opening may be defined to be slightly larger than the distal end of the fixation apparatus, and the body portion may comprise outer surfaces which taper outwardly from the distal end. Further, one or more slots may be provided at the distal end of the fixation apparatus so as to define two or more leg members. In turn, the inventive method may include the step of axially advancing the distal end into an ossicular opening, wherein one or more of the leg members contacts a sidewall in the opening and is deflected towards a center axis of the fixation apparatus to achieve lateral loading.

In another approach the inventive method may further provide for lateral loading at an ossicular opening site via activation of a shape memory material. For example, at least a subportion of a body portion of the fixation apparatus may be provided that is activatable at a minimum body temperature to change from a first configuration to a second configuration, wherein the body portion contacts the internal sidewalls at an ossicular opening when activated to apply a lateral loading force thereto.

In yet another approach, a shape memory spring member may be located about or within a distal end slot of the body portion of a fixation apparatus and actuated at a minimum body temperature to change from a first to second configuration. Upon activation, the spring may contact and displace the body portion to apply a lateral loading force to the internal sidewalls of an ossicular opening.

One or more of the above objectives and additional advantages may be realized by an inventive implantable hearing aid actuator comprising a transducer and an apparatus responsive to the transducer to communicate axial vibrations to an ossicular chain of a patient. According to this characterization, the apparatus includes at least one surface discontinuity formed in the apparatus and located on the apparatus for inducing patient tissue attachment thereto. As will be understood, the at least one surface discontinuity may comprise one or more of the above-noted features.

In one aspect of the present actuator, the at least one surface discontinuity may be integrally formed in the apparatus. In particular the at least one surface discontinuity may be integrally formed in a distal end of the apparatus for inducing tissue attachment subsequent to a direct physical contact with a member of the ossicular chain of a patient (e.g., the incus).

In another aspect of the present actuator, the apparatus may be a separate structure from the transducer that is separately connectable to both the transducer and the member of the ossicular chain. For such purposes, and by way of example only, the apparatus may comprise a wire, tube, pin etc. that is insertable through an aperture of the transducer where it is connectable both to the ossicular member and to the transducer. According to this characterization, the apparatus may be constructed from any material of sufficient rigidity for the transmission of vibrations from the transducer to the ossicular member.

In another aspect of the present actuator, the apparatus may comprise first and second apparatus members that are selectively connectable and disconnectable. According to this characterization, the first apparatus member may be designed to couple with an ossicular member and may include the at least one surface discontinuity located and adapted for inducing patient tissue attachment between the ossicular member and the first apparatus. The second apparatus member, in turn, may be connectable to the transducer and the first apparatus and is responsive to the transducer to communicate axial vibrations from the transducer to the first apparatus.

According to one arrangement of the above noted actuator, the at least one surface discontinuity may comprise at least one of a complex surface shape, surface pores, and surface asperities. According to another arrangement of the above noted actuator, the at least one surface discontinuity may comprise at least one slot extending across and rearwardly through a body portion of the apparatus, from a distal end of the apparatus, to define at least two deflectable leg members. In this regard, a first outer surface portion of each of the at least two leg members may taper outwardly from the distal end, while a second outer surface portion of each of the at least two leg members may taper inwardly from the corresponding first outer surface portion.

According to another arrangement of the above noted actuator, the at least one surface discontinuity may comprise two transverse slots extending across and rearwardly away from the distal end to define four leg members. According to another arrangement of the above noted actuator, the at least one surface discontinuity may comprise a selectively actuatable spring member comprising a shape memory material positionable in the at least one slot. According to another arrangement of the above noted actuator, the at least one surface discontinuity may comprise at least one pair of adjacent enlarged and reduced sections that define a stepped-down lip between the enlarged and reduced section. According to another arrangement of the above noted actuator, the at least one

surface discontinuity may comprise at least one hole extending crosswise through the apparatus. According to another arrangement of the above noted actuator, the at least one surface discontinuity may comprise at least one pair of adjacent enlarged and reduced sections in the apparatus that define a step between the enlarged and reduced section. In particular, according to this arrangement it is preferable that at least a distal one of the enlarged sections is a frusto-conical configuration. According to another arrangement of the above noted actuator, the at least one surface discontinuity may comprise a plurality of frusto-conical sections spaced along a body portion of the apparatus. According to another arrangement of the above noted actuator, the at least one surface discontinuity may be defined by an outer surface having at least one of the surface pores and the surface asperities. According to another arrangement of the above noted actuator, the apparatus may comprise a vibratory member connected to and extending away from the transducer.

Additional aspects and advantages of the present invention will be apparent to those skilled in the art upon review of the further description that follows:

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates one embodiment of a fixation apparatus implemented with an exemplary implantable hearing aid actuator.

Fig. 2 illustrates in cross-section the exemplary implantable hearing aid actuator of Fig. 1 as positioned within the mastoid process of a patient.

Figs. 3A, 3B and 3C illustrate the side, top and perspective views, respectively, of the fixation apparatus embodiment shown in Figs. 1 and 2.

Fig. 4 illustrates the fixation apparatus embodiment shown in Figs. 1, 2 and 3A-3C located within an opening defined in one member (e.g., the malleus) of the ossicular chain of a patient.

Figs. 5A, 5B and 5C illustrate side, end and perspective views, respectively, of an alternate fixation apparatus embodiment.

Figs. 6A, 6B and 6C illustrate side, end and perspective views, respectively, of yet another fixation apparatus embodiment.

Figs. 7A, 7B, 7C and 7D illustrate side, end, perspective and front views, respectively, of an additional fixation apparatus embodiment.

Figs. 8A, 8B, 8C and 8D illustrate side, end, perspective and front views, respectively, of another fixation apparatus embodiment.

Figs. 9 and 10 illustrate additional embodiments of a fixation apparatus implemented with an exemplary implantable hearing aid actuator.

## DETAILED DESCRIPTION

Figs. 1 and 2 illustrate one embodiment of a fixation apparatus 100 comprising the present invention as implemented with an exemplary implantable hearing aid actuator 10. In the latter regard, the exemplary actuator 10 may be utilized with a carrier assembly 20, swivel assembly 40 and mounting assembly 60 to achieve the desired positioning of fixation apparatus 100 within the mastoid process of a patient. Generally, exemplary actuator 10 may be supportably connected to one end of the carrier assembly 20 and carrier assembly 20 may be supportably received through the swivel assembly 40. The assembled carrier assembly 20/swivel assembly 40 may be supportably interconnected to the mounting assembly 60 when attached to a patient's skull.

More particularly, mounting assembly 60 may comprise a mounting apparatus 62 that includes a barrel portion 64 positionable through an opening formed in the mastoid process of a patient to yield access therethrough to the middle ear. A plurality of mounting legs 66 may be provided at the top end of barrel portion 64 and employed with attachment screws 68 to interconnect the mounting apparatus 62 to a patient's skull.

The carrier assembly 20 may comprise an outer support member 22, an inner-shaft member 24 and a telescoping member 26 having a foot-like bottom end 28 for slidable insertion into a channel 12 provided at the top end of exemplary actuator 10. The inner-shaft member 24 may be threaded on an outside surface for driven engagement with a threaded internal surface of the telescoping member 26. A bushing 30 may be disposed in the top end of the outer support member 22 so as to axially fix the inner-shaft member 24 relative to the outer support member 22 but allow inner-shaft member 24 to be rotated relative to the outer support member 22, e.g., via driven engagement by an accessory tool at the top end of the inner-shaft member 24. Telescoping member 26 may include an outer groove 32 extending along the length thereof to co-act with a restraining pin 34 projecting inward from the outer support member 22. As such, when the outer support member 22 is fixed relative to swivel assembly 40 (as will be further described), inner-shaft member 24 may be rotated at its top end so that the telescoping member 26 and

exemplary actuator 10 interconnected thereto and may be selectively advanced/retracted relative to the outer support member 22.

As noted, carrier assembly 20 may be supportably interconnected to swivel assembly 40. In this regard, swivel assembly 40 may include opposing top and bottom plate members 42 and 44 which are adjoined to capture a rotatable ball member 46 therebetween. The plate members 42, 44, and ball member 46 include apertures through which carrier assembly 20 may be slidably received. The top and bottom plate members 42, 44 may be interconnected via pins 48 in a manner that allows the ball member 46 to rotate relative to the top and bottom plate members 42, 44, absent the application of a compressive force on swivel assembly 40. In the event that a compressive force is applied, the top and bottom plate members may be provided so as to secure the ball member 46 in a fixed position. Further in this regard, ball member 46 may be provided with a plurality of slits so that upon the application of a compressive force separated sections of the ball member 46 may be urged inward towards a center axis to secure the outer support member 24 of the carrier assembly 20 in an axially fixed position.

In view of the foregoing description, it will be understood that the exemplary actuator 10 can be supportably interconnected via slot 82 to carrier assembly 20. In turn, carrier assembly 20 may be slidably located through swivel assembly 40. Then, the interconnected exemplary actuator 10/carrier assembly 20/and swivel assembly 40 may be inserted into the top end of the mounting apparatus 62, whereupon the swivel assembly 40 may supportably rest upon a bottom support ledge 70 provided at the bottom end of the barrel portion 64 of mounting apparatus 62.

The interconnection between carrier assembly 20 and swivel assembly 40 provides for pivotable, lateral positioning of the footed end 28 of the carrier assembly 20 and of the actuator 10 interconnected thereto. Further, the carrier device 20 may be selectively secured at a continuum of positions relative to the swivel assembly 40, thereby facilitating advancement/retraction of the carrier assembly 20 and interconnected actuator 10 in a depth dimension. To lock in a given angular and linear position of carrier assembly 20 relative to swivel assembly 40, a locking member 72 may be threadable advanced in the top of the barrel portion 64 of the mounting apparatus 62 so as to apply a compressive force to the swivel assembly 40.

As shown in Fig. 2., the exemplary actuator may comprise an electromechanical transducer 14 with an interconnected vibratory member 16. The transducer 14 may be

located within an outer housing 18 with the vibratory member 16 extending through an opening provided on one side of the housing 18. The distal end of the vibratory member is interconnected to a distal sleeve 11. In turn, a bellows member 13 that is interconnected to the distal sleeve 11 and a proximal sleeve 15 is interconnected to the transducer housing 18. By virtue of this arrangement, axial-vibrations can be communicated between vibratory member 16 and the ossicular chain of a patient, while maintaining isolation of the transducer 12 and other internal componentry of the actuator 10. Of note, the fixation apparatus 100 may be rigidly interconnected to the distal end of the vibratory member 16 for direct interface with the patient's ossicular chain.

Fixation apparatus 100 is particularly adapted for achieving a high degree of mechanical coupling with a patient's ossicular chain. In particular, fixation apparatus 100 may comprise at least one surface discontinuity that induces patient tissue attachment thereto subsequent to surgical implantation. Such surface discontinuity may be defined in a number of different ways. In the embodiment shown in Figs. 1 and 2, and as more clearly shown by Figs. 3A-3C, one surface discontinuity comprises a first frusto-conical portion 102 adjoining a reduced main body portion 104 to define a protruding lip 106 therebetween. Another surface discontinuity is defined by slot 108 extending across and rearwardly from the distal end of the fixation apparatus embodiment 100. Slot 108 serves to define opposing leg members 110, 112. The noted surface discontinuities provide locations to which patient tissue may readily attach subsequent to surgical implantation, thereby enhancing mechanical coupling between the fixation apparatus 100 and a patient's ossicular chain.

In addition to the noted surface discontinuities, fixation apparatus 100 is capable of further enhanced mechanical coupling when advanced into a shallow opening 116 defined within one of the ossicular bones (e.g., an opening defined in the incus via laser ablation). In this regard, and referring now to Figs. 3A-3C and Fig. 4, an opening 116 may defined in the ossicular bone and sized to be slightly greater in cross-dimension (e.g., diameter) than the corresponding cross-dimension size of the distal end of fixation apparatus 100. As such, upon advancement of fixation apparatus 100 into opening 116, the outwardly tapered surfaces 114 of leg members 110, 112 will engage and provide an outward, or lateral, loading force against the internal wall of the opening 116.

Further in this regard, the fixation apparatus 100 may comprise a biocompatible metal (e.g., titanium, a titanium alloy, platinum, a platinum alloy, or gold-plated stainless

steel), wherein leg members 110, 112 may deflect inwardly (e.g., towards a center axis of fixation apparatus 100) upon contact insertion into opening 116 to achieve a degree of lateral loading. Additionally, it may be desirable to define the leg members 110, 112 so that, during axial advancement into the ossicular opening 116 a ratio of the axial force applied to resultant lateral loading force achieved is about 10 to 1 or less; preferably with axial load maintained at less than about 1.2 grams. For such purposes, leg members 110, 112 may preferably comprise a material having a modulus of elasticity in tension of at least about $1 \times 10^7$.

In an alternative embodiment, one or both of the leg members 110, 112 may comprise a shape memory alloy that is conditioned to be actuated at bodily temperatures so that one or both of the distal ends of leg members 110, 112 move away from each other to apply lateral loading within the ossicular opening 116 after surgical placement. As may be appreciated, in such an arrangement leg members 110, 112 need not be provided with outwardly tapered surfaces 114 for engaging the internal sidewalls of ossicular opening 116, and axial loading during insertion into ossicular opening 116 need not be applied to achieve the desired degree of lateral loading. Rather, such loading may be defined in direct relation to the shape memory attributes of the material comprising the leg members 110, 112.

In addition to the surface discontinuities as noted above, fixation apparatus may further be constructed of a material or in a manner that yields an outer surface having pores or asperities for the infiltration of and interconnection of tissue subsequent to implantation. To achieve such pores, a ceramic, plastic or composite material may be utilized to fabricate fixation apparatus 100 as an integral, one-piece device. Alternatively, fixation apparatus 100 may be defined by a metallic core body, with a ceramic, plastic or composite material coating.

Returning now to the implementation of Figs. 1 and 2, an implantation procedure utilizing fixation apparatus 100 will be briefly summarized. Initially, an opening may be defined in the mastoid process of a patient via drilling. Similarly, an ossicular opening 116 may be defined at a desired location. Thereafter, barrel portion 64 of the mounting apparatus 62 may be inserted through the mastoid process opening. The mounting apparatus 62 may be then secured in a desired position on the skull via the insertion of screws 68 through apertures provided in radiating mounting legs 66.

Following connection of the mounting apparatus 62, the exemplary actuator 10, carrier assembly 20 and swivel assembly 40 may be positioned (e.g., as a unit) within the mounting apparatus 62. In this regard, the opening defined through swivel assembly 40 may be sized for slidable receipt of the outside surface of support member 24 of the carrier assembly 20, so as to allow relative axial positioning of carrier assembly 20. More particularly, an accessory tool (not shown) may be utilized to selectively advance/retract the carrier assembly 20 and interconnected actuator 10 relative to the swivel assembly 40. Additionally, the angular position of the exemplary actuator 10 may be selectively set via use of the accessory tool to affect the movement of the carrier assembly 20 and rotation of ball member 46 relative to the top and bottom plate members 42, 44, of the swivel assembly 40. The actuator is positioned so that fixation apparatus 100 is directed towards and within a predetermined distance range of the ossicular opening 116. Then, the locking ring 72 may be advanced within the barrel portion 64 of the mounting apparatus so as to lock in the set angular orientation and depth setting of the carrier assembly 20. To further advance the fixation apparatus 100, an additional accessory tool may be inserted through locking ring 72 to engage the top end of the inner-shaft 24 of the carrier assembly 20 for driven rotation thereof. In this regard, the threading of the inner-shaft member 26 and telescoping member 28 may be defined so that, for a amount of given rotation of the top end of inner-shaft member 26, a corresponding predetermined linear travel of the telescoping shaft member 28 will be affected. The linear advancement of fixation apparatus 100 into the ossicular opening 116 may therefore be carried out to establish a degree of lateral loading as described above. After positioning of the fixation apparatus 100, placement of and connections between other implanted components of a given hearing aid system may be completed.

Figs. 5A-5C, 6A-6C, 7A-7D and 8A-8D illustrate further fixation apparatus embodiments. In the fixation apparatus embodiment 120 shown in Figs. 5A-5C, first and second frusto-conical portions 122 and 124 are provided with a segment 126 interposed therebetween. As illustrated, two stepped-down lips 128 and 130 are defined in this embodiment for tissue interconnection.

Another fixation apparatus embodiment 140 is shown in Figs. 6A-6C. Fixation apparatus 140 includes body portion 142 divided into four leg portions 144a, 144b, 144c and 144d by transfer slots 146a and 146b which extend from the distal end of the main body portion 142 rearwardly. As shown best by Fig. 6A, the proximal outer surfaces of

each of the leg members angle slightly away from the center axis. Further, tapered surfaces 148 are provided at the distal end of each of the leg members. By virtue of the illustrated configuration, the distal end of fixation apparatus 140 may be positioned in an ossicular opening and, as the fixation apparatus 140 is advanced, increased lateral loading may be achieved.

Referring now to Figs. 7A-7D, yet another fixation apparatus embodiment 160 is illustrated. Fixation apparatus 160 comprises a body portion 162 having two openings 164, 166 defined therethrough at different locations along the length of the body portion 162. As will be appreciated, such openings 164, 166 also accommodate the in-growth of tissue after implantation.

In yet another approach, Figs. 8A-8D illustrate a fixation apparatus embodiment 180 which utilizes a spring member 182 positioned within a slot 184 that extends rearwardly from the distal end of body portion 186. More particularly, the spring member 182 may comprise a shape memory alloy that is actuatable at bodily temperatures to change from a first configuration in which spring legs 182a and 182b are substantially positioned within a common plane to a second configuration in which the free ends of spring legs 182a and 182b move laterally away from the noted common plane. Upon such actuation, leg members 188, 190 are deflected outward to achieve lateral loading.

Fig. 9 illustrates another embodiment of a fixation apparatus 200 comprising the present invention as implemented with another exemplary implantable hearing aid actuator 202. As with the actuator 10, the actuator 202 includes a body 204 and an internally housed driver (not shown). The body 204 is an implantable housing, preferably biocompatible and having a substantially central aperture 206 defined therein between a first end 208 and a second end 210. The actuator body 204 may be constructed in various shapes, e.g., cylindrical or rectangular, as a matter of design choice. The actuator body 204 is mountable subcutaneously within the patient's mastoid process (e.g., via a carrier assembly 212 and pivotable member 218), in proximity to a desired coupling point with the auditory system, e.g., a shallow opening such as 116.

The fixation apparatus 200, according to this embodiment, is a separate structure from the hearing aid actuator 202 that is responsive to the actuator 202 to communicate axial vibrations to an ossicular chain. According to this characterization, the fixation apparatus 200 may be inserted into and through the aperture 206 of the actuator 202

where it is separately connected to both the ossicular chain and the actuator 202, subsequent to positioning and alignment of the actuator 202 in the patient.

In this regard, the fixation apparatus 200 may comprises at least one surface discontinuity integrally formed therein and located to induce patient tissue attachment thereto subsequent to surgical implantation. Further in this regard, such a surface discontinuity may take the form, among other things, of any one of the above-described embodiments. For instance as illustrated above, the surface discontinuity may be defined in a number of different ways. In one example, as shown in Figs. 1-3C, the surface discontinuity may comprise a first frusto-conical portion 102 adjoining a reduced main body portion 104 to define a protruding lip 106 therebetween. Furthermore, the surface discontinuity may be defined by the slot 108 extending across and rearwardly from the distal end of the fixation apparatus 100. In another example, the surface discontinuity may comprise any one of the examples provided in figures 5A-5C, 6A-6C, 7A-7B, and/or 8A-8D. As described above, the noted surface discontinuity provides locations to which patient tissue may readily attach subsequent to surgical implantation, thereby enhancing mechanical coupling between the fixation apparatus 200 and a patient's ossicular chain.

An implementation procedure utilizing the fixation apparatus 200 will now be briefly summarized. Initially, an opening may be defined in the mastoid process of a patient via drilling. Similarly, a shallow opening 116 may be defined at a desired location on the incus 230. Thereafter, a positioning system 214 comprising the carrier assembly 212, the swivel assembly 218, and a mounting apparatus 220, e.g., bone anchor may be utilized to locate and align the actuator 202 relative to the ossicular chain and specifically the incus 230.

In this regard, the actuator 202 is supportably connected to an end of the carrier assembly 212. In turn, the carrier assembly 212 is received in an opening 222 provided in the swivel assembly 218. The carrier assembly 212 and swivel assembly 218 may then be supportably positioned in the mounting apparatus 220. In this regard, the swivel assembly 218 includes opposing, top and bottom plate members 224 and 226, respectively, which capture a rotatable ball member 228 therebetween to form the swivel assembly 218. As will be appreciated, the carrier assembly 212 is movable within the opening 222 in a first dimension, e.g., axially or vertically in the direction (A) relative to the incus 230 to position the actuator 202 proximate the incus 230. Similarly, the ball member 228 of the swivel assembly 218 is initially loosely constrained between the top

and bottom plates, 224 and 226, to permit lateral positioning along arc (B) of the actuator 202. Specifically the axial and lateral alignment of the actuator 202 is to achieve alignment of the aperture 206 with the opening 116 on the incus 230.

Once the actuator 202 is positioned, e.g., alignment of the aperture 206 with the opening 116, a locking nut 232 is rotatably securable within the mounting apparatus 220 to secure the ball member 228, which in turn secures the carrier assembly 212 and fixes the position of the actuator 202. Once the actuator 202 is positioned, the fixation apparatus 200 may be inserted through the aperture 206 such that a distal end including the at least one surface discontinuity is positioned within the opening 116 to induce tissue attachment thereto.

The fixation apparatus 200 is further separately connectable to the actuator 202. According to one example of such an interconnection, the fixation apparatus 200 may be connected to a tube 234 passing through the aperture 206. The tube 234 is in turn movably supported within the aperture 206 via bellows members 236 and 238. In this regard, the bellows members, 236 and 238, each comprise a plurality of undulations that permit the bellows members, 236 and 238, to axially respond in an accordion-like fashion to axial vibrations of the tube 234 by a driver (not shown) of the actuator 202. According to this characterization, the fixation apparatus 200 may be interconnected to the tube 234 via an adhesive, mechanical coupler etc., for instance located in the end 240 of the tube 234. In this regard, both the tube 234 and fixation apparatus 200 may be axially vibrated together via the driver, which may comprise, for instance, a coil and magnet, to acoustically stimulate the incus 230.

It should also be noted that according to this characterization, the bellows members 236 and 238 may also maintain isolation of the internal components of the actuator 202. In this regard, the bellows members, 236 and 238, may be hermetically interconnected to each end of the tube 234 and the actuator body 204 such that they form a seal with the tube 234 to isolate the internal components of the actuator 202 from the introduction of body fluids.

Fig. 10 illustrates another embodiment of a fixation apparatus 300 comprising the present invention, as implemented with another exemplary implantable hearing aid actuator 302. In this case, the actuator 302 is substantially similar to the actuator 202 except that the actuator 302 may be positionally retained within the ball member 228 of the swivel assembly 218. This in turn permits lateral alignment of the aperture 206, along

arc B, with a desired interface point, e.g., opening 116 on the incus 230. As with the above embodiment, once the actuator 302 is laterally positioned, e.g., the aperture 206 is aligned with the opening 116, the locking nut 232 may be utilized to secure the ball 228 around the actuator 302, which in turn secures the actuator 302 in a fixed position relative to the positioning system 214. Once positioned, the fixation apparatus 300 may be inserted through the aperture 206 where it is connected to the incus 230 and actuator 302. In this regard, the fixation apparatus 300 according to the present embodiment comprises a first fixation apparatus member 304 and a second fixation apparatus member 306. The fixation apparatus member 304 is configured to couple with a component of the auditory system such as the incus 230. In this regard, the fixation apparatus member 304 may include at least one surface discontinuity, according to any one of the above-described embodiments, for inducing patient tissue attachment thereto subsequent to surgical implantation. The fixation apparatus member 306, is in turn, configured for insertion through the aperture 206 where it may be connected to both the fixation apparatus member 304 and the actuator 302.

The connection between the fixation apparatus members, 304 and 306, may be made by numerous methods. In this regard, however, it is preferable, but not necessary, that the connection between the fixation apparatus members, 304 and 306, be detachable to achieve specific advantages such as removability of the actuator 302. Further, in this regard, the two-part connection provides a number of other advantages related to the implantation of actuators, e.g., 302 in patients. For instance, the fixation apparatus member 304 may be utilized as a uniform or standard interface on the incus 230 for connection of different actuators as they become known or desired, e.g., next generation actuators. This also facilitates removal and/or repair of actuators as well as replacement of actuators with the mentioned next generation actuators. It is also anticipated that the two-part configuration of the present fixation apparatus 300 in combination with the at least one surface discontinuity will facilitate the initial implantation of the actuator 302 by allowing a surgeon to couple the fixation apparatus member 304 to the incus 230, prior to positioning the actuator 302 within the patient.

The detachable connection between the fixation apparatus members, 304 and 306, also provides the advantage of removability with reduced potential for damage to the incus 230. In this regard, in the event it becomes desirable to permanently remove the actuator 302 from the patient, the fixation apparatus member 304 may be left permanently

attached to the incus 230 without substantially affecting the hearing function. In other words, because of its small size, which is on the order of approximately one (1) millimeter, the fixation apparatus member 304 may be left connected to the incus 230 without affecting operation of the natural mechanical movements of the auditory system. Those skilled in the art will appreciate the numerous advantages this provides in relation to implantable devices. For instance, the induced patient tissue attachment may be achieved during implantation using the at least one surface discontinuity in the fixation apparatus member 304, while permitting the actuator 300 to be later permanently removed from the patient in the event it becomes desirable.

According to the above principles, the fixation apparatus members, 304 and 306, may be any two members that are connectable or positionable relative to each other in a manner that provides for acoustic stimulation of the ossicular chain. In one example according to this embodiment, the fixation apparatus members 304 and 306 form a detachable ball joint connection. In this regard, the fixation apparatus member 304 includes a stud appropriately sized for seating in the opening 116 formed in the incus 230. The stud includes a ball disposed on its distal end to form a detachable connection with the fixation apparatus member 306.

Specifically, the stud is designed for insertion into the opening 116, and includes the at least one surface discontinuity as described in regard to any of the above embodiments to facilitate formation of a fibrous union between the fixation apparatus member 304 and opening 116. In this regard, the ball of the fixation apparatus member 304 is designed to detachably couple with the fixation apparatus member 306. Numerous configurations of the fixation apparatus member 306 may be utilized to achieve the connection with the ball as a matter of design choice. According to one example, however, the fixation apparatus member 306 includes a receiver disposed on its distal end that forms a pocket to receive the ball therein, thereby forming a ball joint connection. In this regard, the receiver may be constructed in the form of a spring type receiver where the ends expand outward as the ball is inserted into the pocket, and snap inward around the ball following insertion as illustrated in fig. 10. The ball is then retained in the pocket via the inward pressure applied by the receiver ends but is also permitted to rotate relative to the receiver. Advantageously, this permits movement of the incus 230 in at least a first dimension relative to the fixed position of the actuator 302 to prevent loading therebetween. Such movement of the incus 230 may be caused by a variety of

circumstances, most notably including swallowing, changes in barometric pressure, e.g., caused by changes in altitude of the patient, tissue growth, and/or swelling after the implantation surgery.

It should also be noted that according to the present example, the length of the fixation apparatus 300 controls the vertical relationship between the actuator 302 and the incus 230. Specifically, while the length of either fixation apparatus members 304 or 306 may be varied as a matter of design choice, it is anticipated that the length of the fixation apparatus member 306 will be varied. In this case, a long fixation apparatus member 306 may be utilized to initially make the connection with the fixation apparatus member 304, and the excess length trimmed substantially flush with the top of the actuator 302 following connection with the same.

In addition to the above-noted alternate fixation apparatus embodiments, additional approaches are contemplated in which an outer collar or ring may be selectively advanced/retracted about the body portion of a fixation apparatus to deflect opposing leg members outward and thereby achieve lateral loading within an ossicular opening.

The description provided above is for the purpose of facilitating an understanding of the various features comprising the present invention and is not intended to limit the scope of protection. Additional embodiments, as well as modifications and extensions will be apparent to those skilled in the art and are intended to be within the scope of the present invention as defined by the claims presented.